UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

JONATHAN A. BLOOM,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Docket No. 5:16-cv-121**
	)	
THOMAS E. PRICE, M.D.	)	
Secretary of the U.S. Department of	)	
Health and Social Services	)	
and Social Services,	)	
	)	
Defendant.	)	

PLAINTIFF'S MOTION FOR ORDER REVERSING SECRETARY'S DECISIONS AND MEMORANDUM OF LAW

MOTION FOR ORDER REVERSING SECRETARY'S DECISIONS

Plaintiff Jonathan A. Bloom, by his undersigned counsel, moves pursuant to 42 U.S.C. §§405(g) and Local Civil Rule 9 for an Order reversing four final decisions of the Secretary denying Medicare coverage for a continuous glucose monitor. The decisions must be reversed because they are arbitrary and capricious, not supported by substantial evidence, and otherwise not in accordance with the law.

MEMORANDUM OF LAW

I. INTRODUCTION

Dr. Jonathan Bloom is a recently-retired dentist and grandfather seeking judicial review of four final decisions (the "Decisions") by the Secretary. Since 2010, Dr. Bloom has sought Medicare coverage for the continuous glucose monitor ("CGM") that has kept him out of the emergency room and alive. He has won many cases through the Medicare appeals process for

CGM claims both before and after the services at issue in this case. To date, eight different Medicare administrative law judges ("ALJ") have approved coverage for Dr. Bloom's CGM, yet the Secretary persists in his refusal to cover the claims at issue in this case. For the Decisions at issue, the Secretary's denials conclude that:

1) although Dr. Bloom will suffer serious medical complications, including possible death, without a CGM, the Secretary finds a CGM is not medically necessary;

2) although a CGM is prescribed by a physician, approved by the FDA, and is acknowledged in clinical practice guidelines and peer-reviewed literature as a medical device, the Secretary holds a CGM serves no medical purpose; and

3) although the Secretary has approved Dr. Bloom's prior and subsequent GCM claims, and has approved more than 40 CGMs for others whose condition is indistinguishable from Dr. Bloom, inexplicitly and inconsistently, the Secretary holds the opposite for the claims at issue in this case.

The Secretary's refusal to cover Dr. Bloom's claims is contrary to the administrative record (the "Record")[1] in this case and is contrary to law. Moreover, these conclusions are not supported by substantial evidence and are arbitrary and capricious. Accordingly, this Court should reverse the Secretary's final Decisions, order Medicare coverage, and bring this saga to a close.

II. STATEMENT OF FACTS

A. Continuous Glucose Monitoring

Many people with diabetes manage their disease by finger stick glucose monitoring and injections of insulin. However, a segment of the diabetic population cannot control their diabetes through conventional care and suffer significant complications including stroke, loss of

[1] The Secretary produced three administrative records in this case and did not Bates number the production sequentially but started each administrative record and supplement with Bates stamp 1. The record associated with the Secretary's February 24, 2016 Decision shall be cited as "Record1"; the record associated with the Secretary's March 23, 2016 Decision shall be cited as "Record2"; the record associated with the Secretary's January 27, 2017 Decision shall be cited as "Record3." Collectively they are referred to as the "Record." For the reader's ease, although documents may exist in all three administrative records, citation will be made primarily to Record3, the most complete record, without redundant citation to Record1 and Record2.

consciousness, and eye/kidney/nerve damage. Uncontrolled diabetes is the number one cause of kidney failure, non-traumatic lower limb amputations, and new cases of blindness among adults. *See* http://www.diabetes.org/diabetes-basics/statistics/?referrer=https://www.google.com/ (accessed June 28, 2017). Because of the significant public health costs, the Secretary urges diabetics to control their diabetes.

The peer-reviewed literature establishes that the longer an individual lives with diabetes,[2] the greater the chances are of developing "hypoglycemic/hyperglycemic unawareness"[3] and the more erratic and more drastically glucose levels will change ("brittle diabetes"). Individuals with diabetes and unawareness lack physical sensations (e.g., sweating or shakiness) that might alert them that their glucose is low or high to enable them to take corrective action. It is estimated that 1 in 20 individuals with brittle diabetes dies each year in sleep due to an undetected fatal low, a.k.a., "dead in bed syndrome."[4] The life expectancy of an individual diagnosed with brittle diabetes between 1950 and 1965 was 53.4 years.

A finger stick blood test indirectly measures blood glucose levels based on the amount of oxygen consumed in a reaction on a test strip that changes color (or causes an electric charge), and an algorithm may display a computed blood glucose level on a reader. Similarly, a CGM uses a needle that is inserted into interstitial fluid, and every five minutes (i.e., 288 times per day) computes and displays the blood glucose levels. Record3 at 208. All CGMs:

1) alert patients of episodes of high glucose levels (hyperglycemia) and low glucose levels (hypoglycemia) so that patients can take action to control their blood glucose and avoid serious medical complications; and

2) provide trend information regarding how quickly glucose levels are dropping or rising.

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[2] Although two types of diabetes exist, as used in this brief, "diabetes" will refer to Type I diabetes.
[3] For the reader's ease, diabetes with hypoglycemic and hyperglycemic unawareness will be referred to as "diabetes with unawareness."
[4] https://www.diapedia.org/acute-and-chronic-complications-of-diabetes/7105157816/dead-in-bed-syndrome (accessed June 14, 2017).

The trend information is used by patients for the immediate short-term management of their diabetes[5] (e.g., "Do I have time to make it to the lunch meeting or should I pull over now and drink juice?"), and are used by clinicians for the long-term management of diabetes (e.g., the patient is experiencing more frequent lows and extreme fluctuations in warm weather and thus should take higher and more frequent doses of glucose in summer months). CGMs have been the subject of multiple published peer-reviewed clinical studies, including large multi-center trials, all of which found improved clinical outcomes for patients who use a CGM. Record3 at 460-466, 471-528, 598-623, 644-725, 732-801.

B. Consensus of Experts

In addition to the numerous peer-reviewed published studies, a broad consensus exists within the medical community that CGMs perform an essential medical function and are recognized as the standard of care for individuals with diabetes and unawareness, both nationally and internationally.[6] The American Medical Association supports Medicare's coverage of CGM. Record3 at 208. Independent government technology assessments find CGMs are reasonable and medically necessary for diabetes with unawareness. *See, e.g.*, Record3 at 529-34. More than 95% of commercial payers cover CGMs as reasonable and medically necessary medical equipment for the management of diabetes with unawareness. Record3 at 208.

C. Dr. Bloom, the Medicare Beneficiary

Dr. Bloom's clinicians prescribed a CGM to enable him to manage his brittle diabetes with unawareness. The Record establishes the following unrefuted facts:

- Dr. Bloom's blood glucose level can significantly change rapidly and inexplicably in a short period. Record3 at 157.

[5] Record1 at 379-380.
[6] Record3 at 455-459, 467-470, 535-596, 624-643, 726-28.

•Dr. Bloom has hypoglycemic diabetes which means he cannot detect a sugar low, an extremely dangerous condition. Record3 at 157.

•Due to his inability to detect low blood glucose, Dr. Bloom repeatedly has been discovered passed out with life-threatening lows and had to be revived with emergency services. Record3 at 153, 155, 159; Record2 at 51.

•A CGM provided a "markedly improved" of Dr. Bloom's blood glucose control and resulted in substantially fewer hypoglycemic events. Record3 at 158.

III. STATUTORY AND REGULATORY BACKGROUND

A. General Background of the Medicare Program

The Medicare Act establishes a program of health insurance for the aged, disabled, and individuals with end-stage renal disease. 42 U.S.C. §§ 1395-1395ccc. This action arises under Medicare Part B. The Secretary, the Federal official responsible for administering the Medicare program, has delegated his responsibility to the Centers for Medicare & Medicaid Services ("CMS"), an agency within the department. In turn, CMS has contracted out many Medicare administrative functions, including payment, to private organizations. *See, e.g.*, 42 U.S.C. § 1395h. The contractors, among other things, process claims and set Medicare policy for a particular geographic region.

B. Medicare Coverage and Payment of Home Blood Glucose Monitors

Durable Medical Equipment ("DME") is a benefit provided by Medicare Part B. Per the Social Security Act:

> The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home . . . whether furnished on a rental basis or purchased, and includes blood testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin.[7]

[7] Social Security Act §1861(n).

Thus, the statute merely provides examples of DME and does not explicitly define the term. CMS has established criteria for a non-listed item to be designated DME. As interpreted:

> Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:
>
> (1) Can withstand repeated use;
> (2) Is primarily and customarily used to serve a medical purpose;
> (3) Generally is not useful to an individual in the absence of an illness or injury; and
> (4) Is appropriate for use in the home.[8]

DME must also be "necessary and reasonable for the treatment of the patient's illness or injury to improve the functioning of his or her malformed body member." Medicare regulations state that "[i]n most instances, no development will be needed to determine whether a specific item of equipment is medical in nature," but if such ambiguity exists, "this development would include the advice of local medical organizations . . . and specialists in the field of physical medicine and rehabilitation."[9] "[P]recautionary-type equipment (such as preset portable oxygen units) . . . are considered nonmedical in nature."[10] If Medicare covers a piece of DME, it covers the disposable supplies necessary for the effective use of the DME.[11]

A National Coverage Determination ("NCD") is "a determination by the Secretary that a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060(a)(1). An NCD is binding on all Medicare contractors, ALJs, and the Medicare Appeals Council ("Council"). 42 C.F.R. § 405.1060(a)(4). CMS issued an NCD relating to durable medical equipment, NCD 280.1. That determination:

1) reiterates the four requirements for an item to be DME;

2) includes exemplars of items considered to be DME; and

[8] 42 C.F.R. §414.202.
[9] Medicare Benefit Policy Manual ("MBPM") Ch. 15, §110.1.B.
[10] Id. at §110.1.B.2.
[11] MBPM Ch. 15, §110.3.

3) indicates that if an item does not appear among the generic categories listed, the Medicare contractors should consider whether an item is covered under Medicare's DME benefit based on the advice of medical consultants by taking into account:

a. whether the item has been approved by the United States Food and Drug Administration ("FDA") and is otherwise generally considered safe and effective; and

b. whether it is reasonable and necessary for the patient.

NCD 280.1 indicates blood glucose monitors are considered to be DME provided the Medicare beneficiary (not a specific device) satisfies certain conditions.[12] Medicare has covered glucose monitors since at least 1995.

C. Local Coverage Determinations and Articles

A Medicare contractor processing claims may (but is not required to) establish a local coverage determination ("LCD") that applies to the claims processed by that contractor. An LCD may not conflict with an NCD. LCDs are based on the peer-reviewed literature, general acceptance by the medical community, and are developed in consultation with the relevant medical community.[13] An LCD that is contrary to the standard of care must be based on sufficient evidence to convincingly refute evidence presented in support of coverage.[14]

Consistent with the NCD, the relevant contractor (National Government Services), issued an LCD indicating the coverage criteria for blood glucose monitors and related supplies.[15] The LCD does not indicate continuous glucose monitors are not a covered service, but includes the relevant billing codes for a CGM. LCDs are not binding on an ALJ although they are entitled to deference. 42 C.F.R. § 405.1062(a). An ALJ can decline to follow an LCD if the ALJ provides a rationale.

[12] Those conditions are specified in NCD 40.2, which states glucose monitors are covered if (1) the patient has a diagnosis of diabetes; (2) the patient can use the prescribed device; and (3) the device is designed for home use.
[13] *See* Medicare Program Integrity Manual ("MPIM"), Ch. 13, §§ 13.7, 13.7.1, and 13.8.
[14] MPIM, Ch. 13, §13.8.
[15] National Government Services LCD 27231.

"Articles" are informal communications issued by contractors without consultation with the relevant medical community. Articles typically addressing billing or coding issues. Articles, by design, do not contain coverage determination – only non-reasonable and necessary language can be communicated through articles. *See* https://www.cms.gov/medicare-coverage-database/ (accessed on June 16, 2017). Billing guidance explicitly is not a coverage policy. Because they should not contain coverage information, Articles are not subject to challenge by Medicare beneficiaries. 42 C.F.R. § 426.325(b)(9).[16] Under Medicare regulations, a contractor's Article is not entitled to any deference.[17] Further, District Courts repeatedly have ruled that Articles are not entitled to deference.[18] Effective January 1, 2007, the Medicare contractor, National Government Services, modified Article A47238, an article on glucose monitors, stating it considered CGMs "precautionary."[19]

D. Appeals of Medicare Claims Decisions

Congress established a five-step process for a Medicare beneficiary to follow to obtain judicial review when dissatisfied with the Secretary's coverage determination of a claim for a device and supplies. The first step in the process is to request redetermination by the Medicare contractor that made the initial negative determination on the claim. 42 C.F.R. §§ 405.940-405.958. For the second step, the beneficiary can request reconsideration by a qualified independent contractor ("QIC"). 42 C.F.R. § 405.960. No hearing is held at these first two steps.

[16] *See* infra, section III, C.
[17] This Court has already ruled on that issue. *See* infra, section III, C.
[18] *See Whitcomb v. Burwell*, 2015 WL 3397697 (E.D. Wis. May 26, 2015) (Record3 at 236-246); *Finigan v. Burwell*, 189 F.Supp.3d 201 (D. Mass. 2016).
[19] Although in May 2017 the Article was revised to remove the statement that CGM is precautionary, the Article remained substantively the same during the relevant period.

If the QIC decision is unfavorable, the beneficiary may request a hearing before an ALJ. 42 C.F.R. § 405.1000. The ALJ reviews the record forwarded by the QIC, and any additional evidence offered by the parties, and conducts a hearing. 42 C.F.R. §§ 405.1000 *et seq*. A Medicare contractor or beneficiary may present witnesses in support of their position. An ALJ is bound to follow an NCD and must give deference to an LCD or explain why the LCD was not followed. "[A]n ALJ may rule that Medicare payment is due on a particular item or services received by a beneficiary, based on the particular circumstances represented by the case, even if the contractor's . . . LCD clearly prohibits payment for the particular services." 68 Fed. Reg. 63693 (Nov. 7, 2003). A beneficiary may appeal an adverse ALJ decision to the Medicare Appeals Council ("Council"). 42 C.F.R § 405.1102. A Medicare contractor can seek a referral to the Council if it believes an ALJ rendered a decision contrary to law. Again, an NCD is binding on the Council. 42 C.F.R. § 405.1060(a)(4). The Council typically does not conduct a hearing or allow oral argument, but has discretion to do so.[20] 42 C.F.R. § 405.1124. The Council's decision is the Secretary's final agency decision for purposes of judicial review. 42 U.S.C. §§ 1395ff(b) and 405(g).

The Secretary's decisions are reviewed under the APA standard and must be based on substantial evidence in the record and must not otherwise be arbitrary, capricious, or an abuse of discretion. 42 C.F.R. § 405.1136(f).

IV. PRIOR ADMINISTRATIVE PROCEEDINGS

A. Dr. Bloom's Appeals

Dr. Bloom was prescribed a CGM in 2006 to enable him to better manage his diabetes. NHIC and the QIC denied the claims variously stating a CGM was a convenience item, it was precautionary, or, with respect to the CGM sensors, they were not durable. Dr. Bloom appealed

[20] The Council did not conduct a hearing for any of the cases underlying this action.

to an ALJ. Dr. Bloom received his first favorable ALJ decision in 2011. To the extent CGM claims were denied, Dr. Bloom continued to appeal the denials to an ALJ. Through June 30, 2017, Dr. Bloom has received eight favorable ALJ decisions,[21] one of which was reversed by the Council and is the subject of this action, and three unfavorable ALJ decisions. Dr. Bloom appealed the unfavorable ALJ decisions to the Council. The Council conceded that Dr. Bloom's CGM system is (1) medically reasonable and necessary to treat his condition; (2) cost-effective for the Medicare program; (3) superior to standard blood glucose monitors in monitoring his glucose levels; and (4) the standard of medical care for Type 1 diabetics with hypoglycemic unawareness.[22]

The Council further stated it "does not question the usefulness of the device to the beneficiary"[23] and "do not question the benefit that the beneficiary derives from the use of CGMs."[24] Nonetheless, the Council, in three Decisions[25] that affirmed the three unfavorable ALJ decisions, and reversed one of the favorable ALJ decisions, stated that a CGM does not "serve a primary medical purpose" and is simply "an added precaution" and thus excluded from coverage by Medicare.

B. Related Administrative Proceedings

Other Medicare beneficiaries have appealed denied CGM claims. More than 40 ALJ decisions have concluded that a CGM was DME eligible for coverage as a Medicare benefit and reasonable and medically necessary for individuals with diabetes and unawareness.[26]

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[21] Four favorable ALJ decisions issued before the Decisions (Record1 at 191-256), and three additional favorable ALJ decisions issued.
[22] Record3 at 13.
[23] Record2 at 23.
[24] Record1 at 11.
[25] Record1 at 1-12, Record2 at 18-28 and Record3 at 3-14 (collectively, the "Decisions").
[26] *See e.g.*, Record3 at 344-454. *See* also http://dparrishlaw.com/medicare-acknowledges-dexcoms-g5-as-a-covered-medicare-benefit/ (accessed June 28, 2017)

In April 2016, the Department of Health and Human Services Civil Remedies Division found that CMS's "long-standing policy of broadly construing the DME benefits category is consistent with Congressional intent" and that "there is no peer-reviewed literature, medical opinions, or even any analysis from an individual with a medical background that supports a conclusion that CGM is never reasonable and necessary irrespective of the beneficiary's condition." The HHS Civil Remedies Division deemed the Article that stated CGM was precautionary to be invalid under the reasonableness standard.[27] Record3 at 209-235.

V. STANDARD OF REVIEW

Under the Medicare statute, 42 C.F.R. § 1395ff(b), the final agency decisions included in this action are subject to judicial review under the applicable provisions of the APA. *Heart 4 Heart, Inc. v. Sebelius*, 2014 WL 3028684, *5 (C.D. Ill. 2014) (treating submission as request to review decision by Medicare Appeals Council rather than summary judgment motion). Accordingly, this Court's review of the Secretary's actions is governed by 5 U.S.C. § 706 of the APA, which requires the Court to determine whether, *inter alia*, his actions are arbitrary and capricious, an abuse of discretion, not based on substantial evidence, or otherwise not in accordance with the law. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414-17 (1971). If so, the Court must set it aside.

In *Motor Vehicle Manufacturers Ass'n of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), the Supreme Court described the "arbitrary and capricious" standard as follows:

[27] A Medicare beneficiary filed an LCD challenge asserting that the Article was a constructive LCD. The HHS Civil Remedies Division found the CGM met the requirements of NCD 280.1 and deemed the Article invalid under the reasonableness standard. CMS appealed the decision and the Board ruled the LCD challenge process could not be used to challenge the Article. Although the decision was vacated on jurisdictional grounds, the substantive ruling, that if the Article had been an LCD it was not supported by substantial evidence, is instructive.

> Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. at 63. Similarly, the "substantial evidence" standard requires an in-depth review of the facts relied upon by the agency in its decision:

> A 'substantial evidence' standard, however, does not permit a court to uphold the Secretary's decision by referring only to those parts of the record which support the [Secretary]. A reviewing court must view the entire record and take account of evidence in the record which detracts from the evidence relied on by the [Secretary].

Tieniber v. Heckler, 720 F.2d 1251, 1253 (11th Cir. 1983); *accord Brown v. Bowen*, 794 F.2d 703, 705 (D.C. Cir. 1986) ("Our review in substantial-evidence cases calls for careful scrutiny of the entire record."); *see also Heart 4 Heart, v. Sebelius*, 2014 WL 3028684 (C.D. Ill)(citing *Clifford v. Apfel*, 227 F.3d 863, 869 (7th Cir. 2000). A reviewing court may uphold agency action only on the basis articulated by the agency in its decision, not on *post-hoc* rationalization offered by the agency or its counsel. *Roddy v. Astrue*, 705 F.3d 631,636, 637 (7th Cir. 2013); s*ee Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 631 n.31 (1980); *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 169 (1962); *Biloxi Regional Medical Center v. Bowen*, 835 F.2d 345, 348 n.12 (D.C. Cir. 1987).

Although deference to the Secretary's actions may be appropriate under certain circumstances, such deference is inappropriate here because the Secretary denied coverage for Dr. Bloom's CGM despite covering CGMs for medically indistinguishable Medicare beneficiaries. In *Malcomb v. Island Creek Coal Co*., 15 F.3d 364 (4th Cir. 1994), the court stated:

> An agency's interpretation of its own regulations is normally entitled to judicial deference. We accord this deference to the agency's interpretation even if the agency has made considered changes in that interpretation because '[a]n initial

> agency interpretation is not instantly carved in stone' and the agency should be free to 'consider varying interpretations and the wisdom of its policy on a continuing basis.' When the agency's varying interpretations of a regulation have not been the result of the agency making considered changes in its policy, but rather of the agency simply acting inconsistently without explanation, however, 'the case for judicial deference is less compelling.' ***Moreover, if the agency's record of unexplained inconsistent interpretation is particularly egregious, the interpretation that the agency applied in the case before the court is entitled to no deference***.

15 F.3d at 369 (emphasis added; citations omitted). In reversing the government, the Fourth Circuit continued:

> We find the interpretation of its cross-appeal regulations that the Board applied in the case at bar to have been shockingly inconsistent with its prior and subsequent interpretations.

Finally, no deference is due to the Secretary's Decisions because they conflict with the Secretary's binding NCD 280.1. *See Sierra Club v. Martin*, 168 F.3d 1, 4 (11th Cir. 1999) (no deference due to agency action which does not follow the agency's own regulations); s*ee also Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504 (1994) (no deference due to agency interpretation that contradicts the regulation's plain language.); *University Health Servs. v. HHS*, 120 F.3d 1145, 1149 (11th Cir. 1997) ("The Secretary's interpretation of her own regulations are 'controlling unless plainly erroneous or inconsistent with the regulation.'") (citations omitted).

VI. ARGUMENT

The Secretary makes fundamental errors in his Decisions. First, the Secretary asserted, without substantial evidence, and contrary to the overwhelming evidence in the Record, that a CGM does not serve a medical purpose and therefore does not satisfy the definition of DME. A CGM is the primary and only means by which certain individuals with diabetes can control their disease, it serves medical purposes not served by any other medical device, and a confirmatory finger stick does not indicate that a CGM serves no medical purpose. Second, the Secretary's

Decisions are arbitrary and capricious because the Secretary did not follow his published policies and has paid for CGMs for medically indistinguishable beneficiaries. Despite the Secretary's NCDs and numerous public statements regarding the need for diabetics to test frequently and control their diabetes, the Secretary denied the claim for a Medicare beneficiary who needs a CGM to control his diabetes and complications therefrom. As explained below, the Secretary's Decisions are not supported by substantial evidence, are arbitrary and capricious, and otherwise contrary to law, and must be reversed by this Court.

A. A CGM Is Primarily and Customarily Used to Serve a Medical Purpose; the Secretary's Contrary Finding is Not Supported by Substantial Evidence.

1. A CGM Is Uniformly Acknowledged as a Medical Device.

CMS has a long history of construing the DME benefit broadly, as Congress intended. Record3 at 229 (citing HCFA Ruling 96-1 at 6 and DAB No. 1999 at 3 (2005)). CMS has observed that "in most instances, no development will be needed to determine whether a specific item of equipment is medical in nature" and that when such "development" is needed, it will be based on consultation with specialists and medical societies. *See* MBPM, Ch. 15, §110.1(B). The FDA, government technology assessments, the National Institutes of Health, the relevant professional medical societies, experts in the care of diabetes and commercial insurance payers deem CGM to be a medical device.[28] No medical expert has opined otherwise.

The Secretary's Decisions and Answer[29] indicate that contrary to the requirements, the Secretary did not consult with or consider the opinions of specialists or medical societies,[30] or

[28] *See* Record3 at 455-801.
[29] The Secretary asserted he lacked sufficient information or knowledge regarding the various cited consensus statements of national and professional organizations recommending CGM, the federally funded technology assessment, peer-reviewed publications, and the widespread acceptance of CGM. *See* Secretary's Answer at 70-74; 77-81.
[30] MBPM Ch. 15, §110.1(B)1.

consider the peer-reviewed literature[31] or standards of medical care,[32]and his Decisions do not reflect either awareness or consideration of the same.

Further, as the Secretary concedes, "precautionary" is not a statutorily defined term. Record3 at 11. However, the exemplar of precautionary equipment, a spare preset oxygen tank, underscores the difference between such a "precautionary device" and a CGM. Precautionary devices are backups generally used episodically. In contrast, a CGM is used for the continuous medical management of diabetes and is the primary method of glucose monitoring for individuals with diabetes and unawareness.

2. A CGM is the Primary Means by which Beneficiaries with Diabetes and Unawareness Control Their Diabetes.

Individuals with brittle diabetes and unawareness are unable to control their diabetes despite conducting multiple finger sticks a day– they cannot catch the rapid and extreme changes in their glucose level and they lack any physical sensations that might otherwise warn them to take corrective action. No one can conduct a finger stick while sleeping – the time when most diabetics suffer fatal lows.[33]

Accordingly, a CGM is the primary means by which such individuals control their diabetes. Because these individuals have such erratic glucose levels, potentially debilitating or fatal lows can occur rapidly without the glucose trend information and alarms provided by a CGM. As a practical matter, such individuals may not be conscious to take any corrective action but for a CGM. A CGM is not a secondary, back up alarm system – it is the primary means by which such individuals control their diabetes and without which they cannot control it. Contrary

[31] Record at 644-725. *See* MPIM §13.7.1 indicating peer-reviewed literature should be considered in making coverage decisions.
[32] The consensus of the medical community is a primary factor in making coverage determinations. *See* MPIM, Ch. 13, §13.7.1.
[33] *See* fn 4.

to the Secretary's assertion that a CGM "is essentially used as an additional precaution" and does not primarily serve a medical purpose,[34] it is the only medical device that allows them to control their diabetes.

3. A CGM Provides Medical Information No Other Medical Device Provides.

In his Decisions, the Secretary asserts that because the CGM's readings should be confirmed by a finger stick before adjusting insulin, a CGM is redundant to a finger stick and serves no medical purpose. The Secretary's Decisions are based on a mistake of fact - a CGM provides actionable medical information that no other medical device provides. Finger sticks do not provide glucose trend information that indicates how quickly a glucose level is changing and whether it is rising or falling. Patients use such trend information in the short term to determine whether an insulin adjustment must be made immediately or whether it can be deferred. Clinicians use trend information for the long-term management of diabetes. A CGM provides a "video" of glucose levels while a finger stick provides a snapshot. Further, a finger stick cannot provide notice of an impending dangerous high or low – critical information, particularly when sleeping or driving.

4. Adjunctive Use/Confirmatory Testing Does Not Negate a Device's Medical Purpose.

The Secretary argues that because the FDA label indicates CGM values should be confirmed by a finger stick, a CGM does not serve as a basis for an insulin adjustment and therefore does not serve a primarily medical purpose. However, such confirmation does not negate a CGM's customary and primary medical purpose. At a minimum, a CGM ensures a finger stick is conducted at the critical moment. Further, even if a CGM is adjunctive to a finger stick (which it is not, it is the primary means of monitoring glucose), such adjunctive use does

[34] Record3 at 11.

not negate its medical purpose as the Secretary has acknowledged in numerous NCDs and coverage policies.

a. An Adjunctive FDA Label Does Not Deprive a Medical Device of a Primary Medical Purpose.

The Secretary's assertion that a CGM does not primarily serve a medical purpose because it is adjunctive to a finger stick is belied by a cursory review of NCD 280.1, a partial list of deemed DME, that reflects Medicare coverage of "augmentative" or "adjunctive" devices: continuous passive motion devices (DME used as an adjunct to physical therapy following surgery); oxygen humidifiers (an adjunct to home oxygen machines, another DME device); muscle stimulators, augmentative and communication devices. As if to underscore the unsoundness of his current position, in NCD 280.1, the Secretary recognizes the primary medical purpose (and covers as DME), a self-contained pacemaker *monitor* that ensures that a pacemaker is functioning properly, i.e., DME whose sole function is to ensure the proper functioning of another medical device.

His position is further belied by a cursory review of his numerous coverage decisions extending Medicare coverage to other "adjunctive" devices and medications.[35] The Secretary also acknowledges the primary medical purpose of numerous medical monitors (including heart monitors, respiratory monitors, oxygen saturation monitors), and Medicare covers them.

[35] *See e.g.*, NCD 10.2 ("TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs, in the treatment of acute pain resulting from surgery"); NCD 20.29 ("the use of [hyperbaric oxygen] therapy is covered as adjunctive therapy"); NCD 270.1 ("The use of ES and electromagnetic therapy for the treatment of wounds are considered adjunctive therapies, and will only be covered for chronic . . . diabetic ulcers, and venous stasis ulcers."); NCD 150.2 (covering a bone stimulator to augment bone repair following surgery).

b. Confirmatory Testing Does Not Negate a Medical Purpose.

The Secretary recognizes the primarily medical purpose and necessity of numerous medical tests that are confirmed by subsequent tests or that direct additional testing. Medicare covers both the first "presumptive" test and the secondary confirmatory test in many circumstances including testing for drugs of abuse.[36] Indeed, Medicare covers entire classes of medical tests that are performed solely on the basis of the results of a first Medicare-covered test, i.e., reflex testing - if the value of the first test exceeds a designated threshold, the second test is performed. Thus, a possible confirmatory test does not impair the primarily medical nature of a CGM. The Secretary cites no authority for his novel statement that a device loses its medical purpose if either a confirmatory test is performed or another medical device is used.[37]

Thus, the Secretary has recognized, through NCD 280.1 and numerous national coverage policies, the primary medical purpose of numerous devices that serve an adjunctive purpose and qualify for coverage under the DME benefit. Further, Medicare covers numerous medical monitors and laboratory tests that prompt secondary testing. A CGM's "adjunctive" FDA approval did not and does not deprive a CGM of its primary and customary medical purpose. Indeed, the Secretary concedes that a CGM is only useful to individuals who have diabetes and it is used to manage that medical condition, i.e., it has no application outside of a medical context.

5. The Lack of Medical Reasonableness and Necessity for Dr. Bloom Is Not Supported by Substantial Evidence.

The Secretary did not undertake a medical reasonableness and necessity analysis because he determined a CGM does not serve a medical purpose. The unrefuted, overwhelming evidence

[36] http://www.palmettogba.com/palmetto/providers.nsf/vMasterDID/A59PK51218?OpenDocument.
[37] The Secretary's logic would make all monitoring devices non-medical or precautionary in nature. For example, a heart monitor would be non-medical because a different medical device, a defibrillator, is required to restart a stopped heart. The Court in *Finigan* noted such logic was "head-scratching" at best. 189 F.Supp.3d at 207 n.6.

in the Record establishes that a CGM was and is reasonable and medically necessary for Dr. Bloom who has brittle diabetes with unawareness, and suffers significant complications resulting in significant cost to Medicare. No clinician reviewing Dr. Bloom's record opined that he did not have a dire need for a CGM.

The Secretary did not discuss Dr. Bloom's medical condition, his inability to detect glucose lows without the CGM, the significant complications that can and have resulted from his hypoglycemic unawareness, his significantly improved control with a CGM, and the significant cost to Medicare when Dr. Bloom is unable to control his diabetes. Not only did the Secretary not discuss the foregoing, but he did not discuss a reason for rejecting the opinion of Dr. Bloom's physicians.

Although a treating physician's determination of medical necessity is not dispositive of Medicare coverage, the Secretary should place significant reliance on such decisions or provide a reasoned basis for failing to do so. *See Klementowski v. Secretary of HHS*, 801 F. Supp. 1022 (W.D.N.Y. 1992) (citing *State of New York v. Sullivan*, 927 F.2d 57, 60 (2d Cir. 1991)). [38] This is especially compelling where, as in the cases herein, there is "no direct conflicting evidence." *Kuebler v. Secretary of U.S. Dept. of Health & Human Services*, 579 F. Supp. 1436, 1438 (E.D. N.Y. 1984). Because CMS has never adopted specific regulations specifying what might constitute medical necessity in each case, reliance on a treating physician's opinion of medical necessity is even more important than in the Social Security context. *See U.S. v. Prabhu*, 442 F. Supp.2d 1008, 1032 (D. Nev. 2006). In fact, the Ninth Circuit has commented that the Secretary should not reject the opinion of a claimant's physician without clear and convincing evidence to do so. *Vista Hill Foundation, Inc. v. Heckler*, 767 F.2d 556 (9th Cir. 1985). Dr. Bloom's treating practitioners' opinions are supported by the medical record, there is no evidence to the contrary

[38] *See* also *Roddy v. Astrue*, 705 F.3d 631,636, 637 (7th Cir. 2013); *Senn v. Astrue*, 2013 WL 63257 (E.D. Wis.).

in the Record, and the Secretary has failed to provide a "reasoned basis" for refusing to accept their opinions. *See Heart 4 Heart*, 2014 WL 3028684, at *8 - 9.

B. The Decisions Are Arbitrary and Capricious Because They Are Inconsistent with NCDs and Previous Decisions.

The Secretary's Decisions are arbitrary and capricious because: (1) they are contrary to final decisions rendered in Dr. Bloom's favor before and after these claims were denied and to more than 40 other final decisions; and (2) they conflict with NCD 280.1. The Secretary repeatedly has found CGMs to be DME and a covered Medicare benefit for Dr. Bloom. *See*, *e.g.*, Record1 at 191-256. Further, the Secretary has found CGMs to be DME and a covered Medicare benefit for other Medicare beneficiaries whose medical condition is indistinguishable from Dr. Bloom's condition. Record3 at 344-454. The Secretary ignores his inconsistent final rulings. Thus, the Secretary's denials are arbitrary and capricious and must be reversed. In *Independent Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1246, 1260 (D.C. Cir. 1996), the court stated:

> The treatment of cases A and B, where the two cases are functionally indistinguishable, must be consistent. That is the very meaning of the arbitrary and capricious standard.

Dr. Bloom's condition did not change, but the Secretary took different positions month to month with respect to coverage – the definition of arbitrary and capricious.

Finally, a CGM satisfies the definition of DME found in NCD 280.1. Coverage of glucose monitors is specifically contemplated in NCD 280.1. No exclusion is made for CGMs. As noted above, the Secretary has issued numerous NCDs extending coverage to "adjunctive" devices, monitors and tests that must be confirmed.

VII. CONCLUSION

The Secretary's Decisions are contrary to law and facts. A CGM performs medical functions not performed by any other medical device and is the only device that enables beneficiaries with diabetes and unawareness to control their disease. It meets the Secretary's definition of DME and is recognized as the standard of care. The Decisions are not supported by substantial evidence in the Record, or any relevant evidence. Further, the Decisions are arbitrary and capricious as they conflict with his NCD and his prior determinations regarding CGM, including determinations for Dr. Bloom. For the foregoing reasons, this Court should grant Plaintiff Bloom's Motion for Order Reversing the Secretary's Decisions.

Dated at Burlington, Vermont this 10th day of July, 2017.

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CERTIFICATE OF SERVICE

I, Craig S. Nolan, counsel for Jonathan A. Bloom, do hereby certify that on July 10, 2017, I electronically filed with the Clerk of Court the following document:

PLAINTIFF'S MOTION FOR ORDER REVERSING SECRETARY'S DECISIONS AND MEMORANDUM OF LAW

using the CM/ECF system. The CM/ECF system will provide service of such filing via Notice of Electronic Filing (NEF) to the following NEF parties:

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